

REMARKS

Claims 1-16, 33 and 34 are pending. Claim 1 has been amended. No new matter has been added. Support for the amendments may be found throughout the specification.

Applicants thank the Examiner for withdrawing the previous rejection of claims over EP 1 157 618 to Ang.

CLAIM REJECTIONS

Rejection under 35 U.S.C. § 103(a)

21 CFR 172.155 in view of Morgan

The Examiner has rejected claims 1-8, 33 and 34 under 35 U.S.C. §103(a) as being unpatentable over 21 CFR 172.155 ("CFR") in view of U.S. Patent No. 5,204,029 to Morgan ("Morgan"). See pages 2-4 of the Office Action. Claims 2-8, 33 and 34 depend from independent claim 1.

The Examiner contends that the "CFR describes where natamycin is permitted in foods as an antimycotic agent. ... It is very well known in the art that fat and wax are typically used to coat quality cheese products ... in order to protect the cheese from the ordinary environment. Given the approved use of natamycin in cheese, it would have been obvious to look for a fat or wax coating that could be used as a vehicle for natamycin." See page 2 of the Office Action. The Examiner further contends that "it would have been obvious to look to Morgan, who teaches powdered microcapsules for use in foods." *Id.*

Applicants have discovered a natamycin dosage form including microcapsules where natamycin is encapsulated within a physiologically acceptable shell to provide a protected food preservative natamycin product. The shell is effective in protecting the encapsulated natamycin from degradation by conditions prevailing in a product whereto the encapsulated natamycin is added and in providing release of the natamycin in the product. See claim 1.

Natamycin is a natural product, which is susceptible to degradation in certain environments and especially under conditions, such as heat, light and acids, typically prevailing in food products and in the production of food products. See pages 1-2 and 6 of the specification. Therefore, it has been found that, in certain applications, natamycin is in need of being initially protected against degradation. *Id.* However, the protective shell also needs to

have the capacity of subsequently releasing the natamycin from within the shell since as long as the shell is intact, it will also effectively prevent the natamycin from contacting the food product and hence also from protecting the food product from spoilage. See page 6 of the specification.

CFR merely states that natamycin "may be applied on cheese as an antimycotic." See page 1. According to the Examiner, the fact that cheese is often protected by fat and wax makes it obvious to protect natamycin with a fat or wax coating. CFR does not teach or suggest any particular delivery system for natamycin, specifically not a natamycin dosage form that includes microcapsules. There would have been no reasonable expectation of success if natamycin were to be protected by the fats and waxes used for protecting cheese as the fat or wax would effectively prevent the natamycin from contacting and destroying the fungi on the cheese. The fat or wax as described in the CFR would not release the natamycin after the initial protecting is no longer needed. CFR does not teach or suggest a natamycin dosage form including microcapsules where natamycin is encapsulated within a physiologically acceptable shell to provide a protected food preservative natamycin product, in which the shell is effective in protecting the encapsulated natamycin from degradation by conditions prevailing in a product whereto the encapsulated natamycin is added and in providing release of the natamycin in the product.

Morgan does not remedy this defect in the CFR. Morgan discloses making microcapsules and that the microcapsules may include anti-mycotic agents (see Abstract and col. 5, lines 39-42). Morgan does not teach or suggest a natamycin dosage form including microcapsules where natamycin is encapsulated within a physiologically acceptable shell to provide a protected food preservative natamycin product, in which the shell is effective in protecting the encapsulated natamycin from degradation by conditions prevailing in a product whereto the encapsulated natamycin is added and in providing release of the natamycin in the product.

Since claims 2-8, 33 and 34 depend from claim 1, they are patentable over the combination of CFR and Morgan for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Thies in view of Stark

The Examiner has rejected claims 1, 6, 9-16, 33 and 34 under 35 U.S.C. §103(a) as being unpatentable over Thies ("Microencapsulation." *Kirk-Othmer Encyclopedia of Chemical Technology*, December 4, 2000) ("Thies") in view of Stark ("Natamycin." *Food Preservatives*, 2nd Edition (2003) p.179-95) ("Stark"). See page 4 of the Office Action. Claims 6, 9-16, 33 and 34 depend from independent claim 1.

The Examiner contends that "Thies discloses all of the ways in which food, pharmaceuticals and biotechnological ingredients may be microencapsulated." See page 4 of the Office Action. The Examiner states that "Stark teaches Natamycin." *Id.* The Examiner alleges that "[i]t would have been obvious to one of ordinary skill in the art to supplement any or all of the many biotechnological applications of microcapsules with natamycin in order to reduce the extent of fungus and mold growth in the product." *Id.*

Thies teaches different ways of making microcapsules. Thies provides a list of "representative examples of capsule shell materials used to produce commercial microcapsules along with the preferred applications." See Table 1 on page 2 of Thies. Thies does not teach or suggest a natamycin dosage form including microcapsules where natamycin is encapsulated within a physiologically acceptable shell to provide a protected food preservative natamycin product, in which the shell is effective in protecting the encapsulated natamycin from degradation by conditions prevailing in a product whereto the encapsulated natamycin is added and in providing release of the natamycin in the product.

Stark teaches the physical and chemical properties of natamycin. See pages 179-181 of Stark. Stark does not remedy the defect in Thies. Stark does not teach or suggest a natamycin dosage form including microcapsules where natamycin is encapsulated within a physiologically acceptable shell to provide a protected food preservative natamycin product, in which the shell is effective in protecting the encapsulated natamycin from degradation by conditions prevailing in a product whereto the encapsulated natamycin is added and in providing release of the natamycin in the product.

Accordingly, claim 1 and claims that depend therefrom are patentable over the combination of Thies and Stark. Applicants respectfully request reconsideration and the withdrawal of the rejection.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance.

Should any further fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

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